



MAIL STOP APPEAL BRIEF-PATENT  
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IN THE U.S. PATENT AND TRADEMARK OFFICE BEFORE  
THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	Appeal No.
Marinus Gerardus Cornelis KIVITS et al.	Conf. 5816
Application No. 10/089,995	Group 1647
Filed July 25, 2007	Examiner S. Shafer

# PROCESS FOR OBTAINING GROWTH FACTOR PREPARATIONS (TGF-BETA AND IGF-1) FROM MILK PRODUCTS HAVING LOW MUTUAL CROSS-CONTAMINATION

## REPLY BRIEF

MAY IT PLEASE YOUR HONORS: January 30, 2008

In accordance with 37 C.F.R. § 41.41, Appellants responds to the Examiner's Answer of November 30, 2007 as follows:

Appellants maintain that parameters such as the type of eluent buffer, salt concentration and/or pH level (see top of pg. 4 of Final Rejection mailed February 26, 2007) needed to practice the claimed process would be within the purview of one skilled in the art.

Indeed, none of these parameters are taught as being essential or critical to practice the claimed invention. As to the step of eluting a basic fraction from a cation exchange column, the specification at page 4, line 31 to pg. 5, line 29

discloses the preferred type of resins, temperatures, eluent buffers, salt concentrations (i.e., for adsorption step) and pH levels that can be utilized in the claimed invention.

While a particular salt concentration for the step of eluting the basic fraction is not recited in this passage, one skilled in the art would be able to select a salt concentration by taking into consideration the product being eluted, buffer being used, and additional process conditions when selecting the buffer and concentration of the buffer. Accordingly, appellants submit that any undisclosed information necessary to practice the invention would be within the purview of one skilled in the art. Indeed, a patent specification need not teach, and preferably omits, what is well known in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

Furthermore, the working examples set forth in the specification do exemplify particular buffers and salt concentrations. Contrary to the assertions of the Examiner's Answer on pg. 6, the examples do not stand in contrast with the claims but merely reflect the preferred embodiments of the invention. The working examples do not suggest or state that particular buffers, salt concentrations and/or pH levels are required to practice the claimed invention.

As to the citation to United States Patent No. 5,596,082, which relates to a process for isolating

lactoperoxidase and lactoferrin from milk or milk derivatives, appellants understand that the determination as to whether an invention satisfies the enablement requirement is made on an application by application basis. Nevertheless, appellants note that claim 1 of United States Patent No. 5,596,082 is as follows:

1. A process for isolating lactoperoxidase and lactoferrin from milk or milk derivatives, comprising the following steps:

a) adsorbing the lactoperoxidase and lactoferrin to a cation exchanger having a mean particle diameter of from 100  $\mu$ m to 300  $\mu$ m by passing the milk or milk derivatives over the cation exchanger at a superficial velocity of at least about 600 cm per hour and a liquid load between about 100 and 600 bed volumes per hour; and

b) eluting the lactoperoxidase and lactoferrin with at least one salt solution to form at least one eluate.

In view of the disclosure and claims, it is apparent that United States Patent and Trademark Office did not consider the particular type of buffer or salt concentration as an essential feature that needed to be recited in the broadest claim, or that the selection of such parameters would be unpredictable.

As to whether the scope of the claims constitutes an "invitation to experiment", it respectfully noted that the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom.*,

*Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Indeed, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). In this regard, appellants submit that the Patent Office simply has not provided any evidence to date that would suggest the selection of an eluent buffer, salt concentration and/or pH level would constitute an undue burden on one skilled in the art in view of the present disclosure and claimed invention.

The Examiner's Answer cites to several publications (i.e., SHING et al., BELFORD et al., KUSSENDRAGER et al., QUINQUE et al., and KUSSENDRAGER et al.) in support of its position. The publications may disclose preferred and/or particular parameters but do not suggest that the selection of eluent buffers, salt concentrations and/or pH levels would be an unpredictable task or difficult for one skilled in the art. In fact, none of the publications that a particular eluent buffers, salt concentrations and/or pH levels are essential. Indeed, appellants believe that the publications actually show that one skilled in the art would know or be able to select the type of eluent buffer, salt concentration and/or pH levels needed to

practice the claimed invention. As a result, it is believed that the Examiner's Answer fails to provide any evidence that satisfies the burden of showing that the claimed invention is not enabled by the present disclosure.

One skilled in the art would also be able to elute the hydroxyapatite column sequentially with at least two eluents of increasing pH concentrations. Both independent claims recite that the first and second eluents have a pH of 5.5 to 7. Thus, the claims already provide guidance as to the initial pH concentrations that are used to practice the claimed invention. Furthermore, the specification discusses preferred resins and process parameters at page 6, lines 12-24. Appellants also note that the working examples provide additional guidance as how to elute the hydroxyapatite column.

As to the particular type of fractions obtained with the claimed process, appellants respectfully maintain that these recitations provide further guidance to one skilled in that art as how to practice the claimed invention. Any process parameters or conditions that did not provide these "specifically identified characteristics" would be excluded from the claims.

Thus, appellants believe that one skilled in the art would be able to elute the hydroxyapatite column as recited in the claimed invention in light of the disclosure and knowledge available to one skilled in the art.


As to eluting the hydroxyapatite column with a third eluent having increased salt content or pH as compared to the first and second eluents, one skilled in the art would also take into consideration the salt concentrations and pH already utilized in the first two buffers. Appellants also note that the working examples also provide additional guidance as how to elute the hydroxyapatite column.

Thus, one skilled in the art is provided sufficient guidance so as to be able to elute the hydroxyapatite column with a third eluent having increased salt content or pH as compared to the first and second eluents.

For all the reasons provided above, Appellant respectfully requests that the present rejections be reversed as to all claims.

Respectfully submitted,

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